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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,672	01/21/2004	David S. Garvey	102258.137US1	1938

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EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/760,672	<b>Applicant(s)</b> GARVEY ET AL.	
	<b>Examiner</b> Maury Audet	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-25 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/05/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's response of 07/27/2005 is acknowledged. Claims 6-25 are pending and examined on the merits as drawn to methods of treating gastrointestinal disorders using a compound of formula II (e.g. SPM 3672, 4757, , 5185, 5186, 6372). Due to the recitation of new art and a new rejection under 35 USC 112 1<sup>st</sup>, the present action is made NON-FINAL.

#### ***Claim Objections***

Claim 12 is objected to because of the following informalities: a period is missing at the end of the sentence. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 9, 11, 13, 18, 19, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugan et al. (US 6,143,746).

Daugan et al. teach composition comprising a compound of formula II (namely SPM 3672) for the treatment of various diseases, including peptide ulcers (claims 1 and 12); as well as compositions with carriers (col. 9, line 35).

If not expressly taught therein, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat gastrointestinal disorders such as peptide ulcers,

Art Unit: 1654

using a compound of formula II (SPM 3672) in Daugan et al., because the references expressly teaches that peptic ulcers, a known gastrointestinal disorder, is the one of the disorders contemplated for being treatable using a compound of SPM 3672. One of ordinary skill in the art would have been motivated to treat peptide ulcers, and other related gastrointestinal disorders, using SPM 3672, based on the teachings of Daugan et al. (It is noted that the reference does not appear to provide motivation for the use any other compounds of formula II, in the methods of treating gastrointestinal disorders such as peptic ulcers, other than SPM 3672, the only compound clearly identified in the compound search of the reference).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Claim Rejections - 35 U.S.C. § 112 1<sup>st</sup> Scope of Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-25, specifically as recited in claims 6, 11, and 18, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating gastrointestinal disorders using compounds of formula II (as well as other agents therewith), does not reasonably provide enablement for *preventing* gastrointestinal disorders using compounds of formula II (as

Art Unit: 1654

well as other agents therewith). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated/disclosed that the compounds of formula II (and other agents therewith) may be used for treating gastrointestinal disorders and/or reducing the risk thereof. However, the claims also encompass using the claimed composition to prevent the same, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does the term "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing gastrointestinal disorders such as ulcers (which clearly is not recognized in the medical art as being a totally preventable condition).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the claimed composition which would function to entirely prevent gastrointestinal disorders using compounds of formula II (as well as other agents therewith).

#### ***Allowable Subject Matter***

Claims 6-25, as drawn to the respective methods of treating gastrointestinal disorders using compounds of formula II (notwithstanding the outstanding rejections as to Compound SPM 3672 under section 103 above and the 112 1<sup>st</sup> scope of enablement as to "prevention" and

Art Unit: 1654

objection), are not reasonably taught or suggested by the prior art of record. Were the rejections successfully argued or the claims amended to overcome the rejections, the claims would like receive favorable consideration.

***Conclusion***


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 04/15/2006

  
MAURY AUDET  
PATENT EXAMINER  
ART UNIT 1654